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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,881		Sander Jan Hendrik Van Deventer	28902.nob11	6763

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EXAMINER	
LIETO, LOUIS D	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/506,881	VAN DEVENTER ET AL.	
	Examiner	Art Unit	
	Louis D. Lieto	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *10-19 and 23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 20-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/07/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response to the Restriction requirement was received on 4/26/2006. Claims 1-17 and 20-23 are pending in the instant application. Applicant's election with traverse of Group I, claims 1-9, 20-22, drawn to a method for producing mononuclear cells over-expressing IL-10, wherein the proliferating agent is an anti-CD3 antibody, is acknowledged.

Claims 10-19 and 23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/26/2006.

Response to Arguments

Applicant's election with traverse of Group I in the reply filed on 4/26/2006 is acknowledged. Applicant is correct in assuming that the alternative embodiments of anti-CD28 and phytohemagglutinin will be examined together with anti-CD3. Applicant argues that the method of claim 10 should be examined together with invention of group I. This is not found to be persuasive. First, applicant has provided two copies of claim 10 in the claims filed on 4/26/06. Therefore it is not possible to determine which claim 10 applicant's arguments are directed towards. Further, a pharmaceutical composition is patentably distinct from mononuclear cells that overexpress IL-10. This is due in part to the fact that the pharmaceutical composition may comprise further components in addition to said cells. Further, as previously stated: the claimed subject matter was known from the prior art document of Symonds et al., the subject matters of claims 1-17, 20-23 are not so linked as to form a single general inventive concept (Rule 13.1

PCT) as they appear not to be linked by a new and inventive common special technical feature in the sense of Rule 13.2 PCT by taking into account the state of the art. Therefore restriction is proper.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-9, 20-22 are under consideration.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Objections

Claim 10 objected to because of the following informalities: There are two copies of claim 10 filed in the claims of 4/26/06. Appropriate correction is required.

Claim 22 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 22 limits the nucleotide sequence of claim 9 to encoding IL-10. However, claim 9 depends from claim 1, which states that the nucleotide sequence encodes IL-10. Therefore Claim 22 fails to further limit the preceding claims. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 9, 20 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Moritani et al. {Moritani (1996) J.Clin Invest. 98:1851-1859.

Moritani et al. provides guidance on the isolation of PBMC TH1 cells from mice, isolation of single cell clones, culturing the TH1 cells with Ag and radiation sterilized APCs so as to increase their proliferation, and transfecting the cells with a construct encoding IL-10 and a *neo* cassette (pg. 1851-1853, Methods). Th1 cells are inherently CD4+ T cells. Further, Moritani et al. teaches the enrichment of the transfected population by culturing the cells with increasing levels of G418, so as to select for TH1 cells that express IL-10 (pg. 1853, Col.2). By gradually increasing the levels of G418, Moritani et al. is selecting for cells that overexpress *neo* and consequently IL-10. Finally, Moritani et al. teaches that the enriched Th1 cells are transferred into NOD mice. Thus, by teaching all the limitations of the claims as written, Moritani et al. anticipates the instant invention as claimed.

Claims 1-8, 20 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Setoguchi et al. {Setoguchi et al. (2000) 165 :5980-5986).

Setoguchi et al. provides guidance on a method of isolating splenocytes from mice immunized with OVA or without OVA, proliferating them for 48 hours in the presence of OVA for OVA specific splenocytes or PHA for Ag non-specific splenocytes and transfecting them with a vector encoding IL-10 (pg. 5981, Materials and methods; pg. 5983, col. 1). Further, Setoguchi et al. teaches the enrichment of the splenocytes, post transfection, for CD4+ T cells by using MACS columns (pg. 5981, col.2). Finally, Setoguchi et al. teaches transferring the CD4+ T cells to mice (pg. 5981, col. 2). Thus, by teaching all the limitations of the claims as written, Setoguchi et al. anticipates the instant invention as claimed.

Claims 1-6 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2001/0033836 A1 published (10.25.2001) priority to (9.19.1997), hereafter known as Symonds et al.

Symonds et al. provides guidance on the isolation of CD4+ cells from peripheral blood collected from an individual with rheumatoid arthritis (pgph 21, 59, Claim 1). Wherein the cells are enriched for CD4+ cells by FACS or column enrichment (pgph 14). These cells are cultured with chicken or bovine collagen type II or autologous synovial fluid in the presence of autologous Epstein Barr virus-transformed B-cells (LCL), dendritic cells or other antigen-presenting cells, or OKT3-anti-CD3 antibody (pgph 55,59). CD4+ cells reactive to collagen type II or antigens within synovial fluid are then expanded in the presence of interleukin-2. The gene encoding IL-10, is introduced into the CD4+ cells via a retroviral vector. The transduced cells are expanded and injected into patients via the intravenous route (pgph 59). These cells are

CD4+ but are not selected for a specific antigen. Thus, by teaching all the limitations of the claims as written, Symonds et al. anticipates the instant invention as claimed.

No claims allowed.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Lou Lieto whose telephone number is (571) 272-2932. The examiner can normally be reached on Monday-Friday, 9am-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Patent applicants with problems or questions regarding electronic images that can be viewed in the PAIR can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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